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IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE AT NASHVILLE

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U.S. DISTRICT COURT
MIDDLE DISTRICT OF TN

IRENE JENKINS,	)	**BISPHOSPHONATE LITIGATION**
	)	
Plaintiff,	)	**CASE NO.** 3 06 0772
	)	
vs.	)	**JUDGE:** Campbell
	)	
NOVARTIS PHARMACEUTICAL CORPORATION,	)	**MAGISTRATE:** Brown
	)	
Defendant.	)	**JURY DEMAND**

COMPLAINT

Plaintiff brings this pharmaceutical liability action individually against Novartis Pharmaceutical Corporation, who manufactured AREDIA, and he states to this Court the following facts and his claims for relief:

01. Plaintiff Irene Jenkins is a citizen of the State of Tennessee. She resides in Loudon County. A doctor prescribed her AREDIA. As a result, she suffered osteonecrosis of the jaw.

02. Defendant Novartis Pharmaceutical Corporation ("Novartis") is a Delaware corporation with its principal place of business located at One Health Plaza, East Hanover, New Jersey 07936-1080.

04. During all times relevant hereto, Novartis was in the business of manufacturing, marketing, distributing, promoting, testing, labeling, and selling AREDIA.

05. This Court has *in personam* jurisdiction and venue. Novartis markets AREDIA to physicians in Tennessee so that they will prescribe it to their patients in Tennessee. Novartis

distributes and sells AREDIA to patients in Tennessee. Novartis compensates agents who "pitch" the drug to doctors here in Tennessee. Novartis sends instructional materials about the drug and other Novartis products to patients and physicians in Tennessee. Novartis profits from health maintenance organizations administered in Tennessee. Patients in Tennessee remit a co-payment to pharmacists when purchasing Novartis products. Novartis profits from patients in Tennessee who use its medications. Novartis "resides" in Davidson County though its agents.

06. AREDIA is a bisphosphonate. The principal pharmacologic action of AREDIA is inhibition of bone resorption. Bisphosphonates prevent and treat osteoporosis in post-menopausal women. Stronger forms of bisphosphonates are used in the management of advanced cancers that have metastasized to the bone. When bisphosphonates are given in cancer chemotherapy, drugs like AREDIA are given intravenously and usually for longer periods.

07. Taking AREDIA increases the risk of osteonecrosis of the jaw, including the maxilla (bone). Taking AREDIA causes osteonecrosis of the bone. Novartis made labelling changes in September and October of 2003, but these changes were inadequate to warn consumers and remain so to this date.

COUNT I. STRICT LIABILITY

08. Novartis was engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing AREDIA in interstate commerce, which it then sold and distributed throughout the world. Therefore, Novartis is a manufacturer and this is a product liability action as specified by Tennessee common law.

09. The Plaintiff was taking AREDIA in a reasonably foreseeable manner.

10. AREDIA reached her without a substantial change in condition.

11. She was not aware of and reasonably could not have discovered the specific danger of severe osteonecrosis associated with the use of AREDIA.

12. AREDIA increases the risk of osteonecrosis of the jaw. AREDIA causes osteonecrosis of the jaw. Therefore, AREDIA is an "unreasonably dangerous / defective products" as specified by Tennessee common law due to Novartis' failure to warn the Plaintiff.

13. This unreasonably dangerous / defective drug increases the risk of osteonecrosis of the jaw. This drug causes bisphosphonate-induced osteonecrosis. The Plaintiff has suffered osteonecrosis of the jaw. She has sustained compensatory damages in an amount to be proven at trial.

14. Merck also acted recklessly as defined by the Tennessee Supreme Court in *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn.1992). Therefore, the Plaintiff seeks imposition of punitive damages in order to punish Novartis and deter other drug companies from the same wrongdoing.

COUNT II. NEGLIGENCE

15. Novartis owed the Plaintiff a common law duty to use reasonable care in manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, and advertising of AREDIA. This duty included a warning about the danger of bisphosphonate-induced osteonecrosis.

16. Novartis breached that duty of care in one or more of the following respects:

a. Failing to test and inspect AREDIA in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;

b. Failing to utilize and implement a reasonably safe design in the manufacture of AREDIA;

c. Failing to manufacture AREDIA in a reasonably safe condition;

d. Failing to warn the Plaintiff of the danger of bisphosphonate-induced osteonecrosis;

e. Failing to label AREDIA reasonably so as to warn the Plaintiff of the danger of bisphosphonate induced osteonecrosis; and

f. Manufacturing AREDIA, which is an unreasonably dangerous / defective drug.

17. Furthermore, Novartis is guilty of negligence *per se*. Novartis violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*, and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations. Novartis' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se*.

18. Novartis failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. The Plaintiff is part of this class. Therefore, Novartis is negligent *per se* in the following respects:

(a) The labeling lacked adequate information on the use of the drugs AREDIA (21 C.F.R. Section 201.56[a] and [d]);

(b) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57[e]);

(c) There was inadequate information for patients for the safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]);

(d) There was inadequate information regarding special care to be exercised by

the doctor for safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]); and

(e) The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

19. Novartis' negligence is the proximate cause of all damages. The Plaintiff has suffered osteonecrosis of the jaw. She has sustained compensatory damages in an amount to be proven at trial.

WHEREFORE, the Plaintiff requests that a jury be impaneled and that this Court award compensatory damages and punitive damages in an amount specified by the jury.

Respectfully submitted,

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